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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/552,660	Applicant(s) HONG, YAN	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☒ Claim(s) 15 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Remark

The present Office communication addresses the claims which were amended and received by the Office on February 17, 2005.

Therefore, the present Office Action will supercede all objections and/or rejections made in the previous Office Action mailed on July 5, 2007.

Claims 1-21 are pending and are under prosecution herein.

Claim Objections

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 15 depends from claim 14, which recites that the kit comprises a luciferin and a luciferase.

Claim 15 then recites that the kit comprises ATP sulfurylase and luciferase.

ATP sulfurylase falls outside of the scope of the parent claim 14 which recites that luciferin and luciferase is employed.

The rejection can be overcome by changing the dependency of claim 15 to depend from claim 13; or amending claim 15 to recite, "wherein the detection enzyme further comprises ATP sulfurylase."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1637

Claims 2-12 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase, "adding an oligonucleotide primer to the sample which hybridizes to the transgene," then subsequently states, "subjecting the sample nucleic acid and primer to a polymerase reaction."

It is unclear whether the sample nucleic acid is referring to the transgene, or some other nucleic acid.

Claims 2-12 and 20 are indefinite by way of their dependency on claim 1.

Claim 6 recites the phrase, "performed substantially simultaneously."

A process can either be subsequent or simultaneously. Therefore, the metes and bounds become unclear whether something is "substantially" simultaneous – what is the difference between a process which is subsequent versus a process which is substantially simultaneous?

Claim 10 recites that the method is for "use" but does not actively require any active limitation to the claim so as to determine the metes and bounds of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1637

Claims 13-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Murray et al. (WO 02/064830 A3, published August 22, 2002).

The present rejection is predicated on the fact that claims do not require that the primers are a component of the kit, but rather, an optional reagent of the kit.

Murray et al. disclose a method of identifying the presence of a target nucleic acid in a sample (page 6, lines 3-9), wherein the method involves a replication of the target nucleic acid, said method comprising the steps of:

- a) detecting the pyrophosphate (PPi) produced by a nucleic acid polymerase enzyme in the presence of dCTP, dGTP, dTTP, primer(s), a DNA template (page 5, lines 21-24); and
- b) detecting the presence of the target nucleic acid by using the generated PPi in a bioluminescence reaction involving ATP sulfurylase and luciferase (page 5, lines 10-15).

The artisans explicitly disclose the use of luciferin, luciferase enzymes in their bioluminescence reaction (page 8, lines 29 and 30).

The artisans explicitly disclose that the reaction is performed, "directly on the reaction mixture used for the enzyme DNA synthesis (i.e., PCR) in the presence of all the components necessary for DNA synthesis (page 5, lines 13-15).

The artisans explicitly employ a d- α -SATP (alpha-thio-dATP; see page 6, lines 21-30).

The artisans explicitly disclose the use of a *Taq* polymerase, which is known and accepted in the art as being thermostable (page 9, line 30).

The artisans explicitly disclose a kit comprising the reagents necessary for their subject method (see claim 17).

Therefore, the invention as claimed is clearly anticipated by Murray et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 11-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. (WO 02/064830 A3, published August 22, 2002) in view of Chen et al. (U.S. Patent No. 6,689,880, issued February 10, 2004, filed September 25, 2001).

The present rejection is based in the interpretation that the primers which hybridize to transgene is present in claims drawn to a kit.

Murray et al. (WO 02/064830 A3, published August 22, 2002).

Murray et al. disclose a method of identifying the presence of a target nucleic acid in a sample (page 6, lines 3-9), wherein the method involves a replication of the target nucleic acid, said method comprising the steps of:

a) detecting the pyrophosphate (PPi) produced by a nucleic acid polymerase enzyme in the presence of dCTP, dGTP, dTTP, primer(s), a DNA template (page 5, lines 21-24); and

b) detecting the presence of the target nucleic acid by using the generated PPi in a bioluminescence reaction involving ATP sulfurylase and luciferase (page 5, lines 10-15), thereby meeting the limitations of claims 2, 3, 5, 11, 12 and 15.

With regard to claims 4 and 14, the artisans explicitly disclose the use of luciferin, luciferase enzymes in their bioluminescence reaction (page 8, lines 29 and 30).

Art Unit: 1637

With regard to claim 6, the artisans explicitly disclose that the reaction is performed, “directly on the reaction mixture used for the enzyme DNA synthesis (i.e., PCR) in the presence of all the components necessary for DNA synthesis (page 5, lines 13-15).

With regard to claims 7 and 8, the artisans explicitly employ a d- α -S-ATP (alpha-thio-dATP; see page 6, lines 21-30).

With regard to claim 13, the artisans explicitly disclose a kit comprising the reagents necessary for their subject method (see claim 17).

Murray et al. do not explicitly disclose that their method should be directed to detecting a transgene.

Chen et al. disclose a method of detection of transgene in a plant sample (column 2, lines 58-61), detection of which involving PCR amplification (column 8, lines 8-23), or pyrosequencing (column 8, lines 43-56).

With regard to claims 16 and 17, Chen et al. explicitly disclose that the transgene confers herbicide resistance (column 2, line 25-30), such as glyphosate (column

Chen et al. explicitly disclose that such method of detection would involve a primer which overlaps from an adjacent genomic DNA and insert DNA junction (one primer in the inserted sequence and one in the flanking genomic sequence) (see column 8, lines 45-49).

Chen et al. explicitly disclose that the complex is incubated in the presence of DNA polymerase, ATP sulfurylase, luciferase, apyrase, adenosine 5' phosphosulfate and luciferin, dNTPs (column 8, lines 50-53).

Chen et al. do not explicitly disclose the actual steps of conducting a pyrosequencing reaction.

Art Unit: 1637

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Murray et al. with the teachings of Chen et al., thereby arriving at the claimed invention for the following reasons.

Chen et al. disclose the importance of producing food products, such as plants with transgenes which confer herbicide tolerance (column 1, line 24) for the purpose of improving agronomic traits and the quality of the product (column 1, lines 22-23).

Murray et al. disclose an efficient method of detecting target nucleic acid in a sample. While Murray et al. do not disclose every possible type of target nucleic acid which could be detected by their method, said one of ordinary skill in the art at the time the invention was made would have been motivated to employ the teachings of Murray et al. for the detection of transgene in a sample, for the advantage discussed by Chen et al., rendering the invention as claimed *prima facie* obvious over the cited references.

With regard to the claims drawn to a kit, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the reagent compositions of Murray et al., and Chen et al., into kits in view of the conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, matched and/or preweighed components, etc.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. (WO 02/064830 A3, published August 22, 2002) in view of Chen et al. (U.S. Patent No. 6,689,880, issued February 10, 2004, filed September 25, 2001), as applied to claims 1-8 and 11-17 above, and further in view of Nyren et al. (U.S. Patent No. 6,258,568, issued July 10, 2001, priority July 23, 1999).

The teachings of Murray et al. and Chen et al. have already been discussed above.

Art Unit: 1637

Neither Murray et al. nor Chen et al. explicitly disclose that the sample DNA or oligonucleotide be immobilized to a solid support, or that a multiplicity of sample DNA sequences are arranged in an assay format on a solid surface.

Nyren et al. disclose a bioluminescence assay employing pyrophosphates (ELIDA), said bioluminescence involving the same luciferase, ATP sulfurylase enzymes, wherein the artisans explicitly disclose the immobilization of the DNA on a solid surface (column 7, lines 57-59) or that the primers are immobilized on a solid surface (column 8, lines 16-18).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Murray et al. and Chen et al. with the teachings of Nyren et al., thereby arriving at the claimed invention.

One of ordinary skill in the art would have been motivated to employ the solid phase format disclosed by Nyren et al., in the method of Murray et al, for the well-known advantage of the solid phase format allowing a plurality of assays to take place simultaneously.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. (WO 02/064830 A3, published August 22, 2002) in view of Chen et al. (U.S. Patent No. 6,689,880, issued February 10, 2004, filed September 25, 2001), as applied to claims 1-8 and 11-17 above, and further in view of Bruce et al. (U.S. Patent No. 6,228,645, issued May 8, 2001, filed December 22, 1997).

The teachings of Murray et al. and Chen et al. have already been discussed above.

Neither of the artisans explicitly disclose that their method should be directed for the detection of detecting a transgene which provide insect resistance.

Art Unit: 1637

Bruce et al. disclose the well-known desire to confer insect resistance in agronomic products such as plants (column 1, lines 50-57).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Murray et al. and Chen et al. for the purpose of detecting the presence of a transgene responsible for producing insect resistance, resulting in the improvement of agronomic traits and the quality of the product (column 1, lines 22-23, Chen et al.).

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. (WO 02/064830 A3, published August 22, 2002) in view of Chen et al. (U.S. Patent No. 6,689,880, issued February 10, 2004, filed September 25, 2001), as applied to claims 1-8 and 11-17 above, and further in view of Zimmermann et al. (Lebensm-Wiss. und-Technologie (November 1998, vol. 31, pages 664-667).

The teachings of Murray et al. and Chen et al. have already been discussed above.

Neither of the artisans disclose the use of SEQ ID Numbers recited in the claims.

Zimmermann et al. disclose a primer mg4 (see Table 1) which is the exact sequence of SEQ ID Number 2, directed to detect transgenes in corn (page 664, 1st column).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Murray et al. and Chen et al. and Zimmermann et al. so as to detect known transgenes from plants.

One of ordinary skill in the art at the time the invention was made would have had a clear expectation of success at combining the teaching provided that Zimmermann et al. already provided the primer sequence which is capable of detecting transgenes in corn samples, allowing said one of

Art Unit: 1637

ordinary skill in the art to employ them in the method produced by the combination of Murray et al. and Chen et al.

With regard to the claims drawn to a kit, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the reagent compositions of Murray et al., Chen et al. and Zimmermann et al., into kits in view of the conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, matched and/or preweighed components, etc.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Double Patenting

Applicant is advised that should claim 20 be found allowable, claim 21 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

No claims are allowed.

Applicants are advised that claims 19-21 embrace nucleic acid sequences which are patentably distinct from each other. Under the normal circumstances, such claims would have been restricted to a single nucleic acid sequence.

However, given the nature of the present application in that the first Office Action had been drawn to claims which were not reflective of the amendment received prior to said first Office Action, the instant Office Action was furnished.

Art Unit: 1637

Applicants, in their response, are requested to elect a single SEQ ID Number (in addition to SEQ ID Number 2 which had already been examined) for the purpose of further prosecution (i.e., restriction requirement).

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

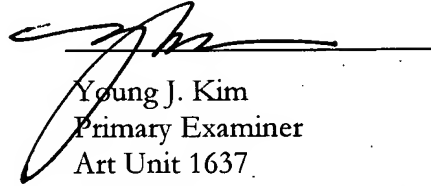
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like

Art Unit: 1637

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1/3/2008

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